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Section 14.0 510(k) SUMMARY

ACMI Invisio IRL Digital Laproscope System

1. Sponsor: ACMI Corporation
136 Turnpike Road
Southborough, MA 01771-2104

Contact: Terrence E. Sullivan
Telephone: 508-804-2739
Date: July 30, 2004

2. Device Name:

Proprietary Name:	ACMI Invisio IRL Digital Laproscope System
Common/Usual Name:	Laparoscope Video Camera and accessories
Classification Name:	Laparoscope Surgical Camera and accessories

2. Predicate Devices:

Circon's USA Series Laparoscope with various Tradenames (K013165)

ACMI Electronic Video Cystonephroscope (ECN) System (K030960)

Olympus Deflectable Tip Video Laparoscope (K955404)

3. Device Description:

The Invisio IRL Digital Rigid Laparoscope is a standard USA Series Laparoscope that incorporates CMOS (complimentary medical oxide semi-conductor) sensor technology to generate an image replacing the rod lens system typically used in the rigid laparoscope The Invisio IRL Digital Rigid Laparoscope can be inserted into the abdomen or chest through small skin cuts allowing the surgeon to explore the whole cavity without the need of making large standard openings dividing skin and muscle.

4. Intended Use:

The Invisio IRL Digital Rigid Laparoscope System is intended for use, by qualified physicians, to provide access to, illumination, and visualization of body cavities, during endoscopic laparoscopic surgical procedures.

5. Technological Characteristics and Substantial Equivalence:

The Invisio IRL Digital Rigid Laparoscope System is substantially equivalent to features incorporated into the following legally marketed predicate devices:

The Invisio IRL Digital Rigid Laparoscope utilizes the rigid laparoscope technology (design and materials) of the following ACMI rigid laparoscope

Circon's USA Series Laparoscope with various Tradenames

The Invisio IRL Digital Rigid Laparoscope system incorporates the video sensor technology located in the distal tip of the endoscope similar to that utilized in the following device:

ACMI Electronic Video Cystonephroscope (ECN) System (K030960)

The Invisio IRL Digital Rigid Laparoscope incorporates the CMOS sensor technology similar to that used in the **ACMI Electronic Video Cystonephroscope (ECN)** System (K030960)

Finally, the Invisio IRL Digital Rigid Laparoscope uses generally similar video processing and imaging technology similar to that used in the **Olympus Deflectable Tip Video Laparoscope** (K955404)

ATTACHMENTS

Number	Description
Attachment 1	System Drawings
Attachment 2:	Invisio IRL Digital Rigid Laparoscope System Specifications (ACMI Engineering Specification)
Attachment 3	Laparoscope Video Subsystems Specifications
Attachment 4	Software Requirements Specification
Attachment 5	Cmos Sensor CMOS Sensor specificationinformation (Micron Tech. Brief MI- 0133)
Attachment 6	System & Software Risk Analysis
Attachment 7	Level of Concern Document
Attachment 8	Product Validation Protocol
Attachment 9	Invisio IRL Digital Rigid Laparoscope IFU
Attachment 10	Circon's USA Series Laparoscope with Various Tradenames
Attachment 11	ACMI Electronic Video Cystonephroscope (ECN) IFU
Attachment 12	Olympus Deflectable Tip Laparoscope Brochure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2004

Mr. Terrance E. Sullivan
Director, Regulatory Affairs
ACMI Corporation
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K042069
Trade/Device Name: Invisio IRL Digital Rigid Laparoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: July 30, 2004
Received: August 3, 2004

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5.0

Indications for Use

510(k) Number (if known): K042069

Device Name: Invisio IRL Digital Rigid Laparoscope System

Indications For Use:

The Invisio IRL Digital Rigid Laparoscope System is intended for use, by qualified physicians, to provide access to, illumination, and visualization of body cavities, during endoscopic laparoscopic surgical procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042069